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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/013,980	11/05/2001	Gust H. Bardy	032580.0060.CIP	3720

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EXAMINER

SCHAETZLE, KENNEDY

ART UNIT	PAPER NUMBER
3762	

DATE MAILED: 11/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/013,980

Applicant(s)

BARDY ET AL.

Examiner

Kennedy Schaetzle

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 September 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance, except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 59-86 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 59-72, 75-77, 79-81, 84 and 86 is/are rejected.
- 7) ☒ Claim(s) 73, 74, 78, 82, 83 and 85 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 November 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>3/11/04</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Specification

1. The disclosure is objected to because of the following informalities: the reference to application 09/941,814 on page 1 must be updated to reflect its abandoned status.

Appropriate correction is required.

Claim Objections

2. Claim 67 is objected to because of the following informalities: the reference to first and second fins lacks antecedent basis. The examiner will assume it was the applicants' intent to recite dependency on claim 66 since first and second fins are recited in this claim. Appropriate correction is required.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1, 59, 61, 64, 66-69, 71, 75-77, 79-81, 84 are rejected under 35 U.S.C. 102(b) as being anticipated by Healy (Pat. No. 4,757,817).

Regarding claim 1, Healy discloses a lead electrode assembly comprising an electrode 13 having a proximal end and a distal end, and top and bottom surfaces (inherent in any multi-dimensional object), a backing layer 14 positioned over the top of the electrode and a fin (tab 10b) projecting from the backing layer.

Regarding the recitation in the preamble concerning the use of a subcutaneously placed implantable cardioverter-defibrillator, the examiner considers such language to represent intended use for the lead electrode assembly.

Regarding claim 59, see Fig. 2.

Regarding claim 64, note cover 10.

Regarding claim 66, the examiner considers the backing layer as discussed above to have first and second backing regions (10a and 10b respectively) with first and second edges meeting at cut 22. The two regions are separated along an indented fin-forming region (that portion of the tab material generally perpendicular to the cut 22 and in the region of aperture 22a that folds to form the tab as best seen in Fig. 2). The fin-forming region is divided into first and second fin sides, with the first side being that portion of the tab sidewall along cut 22, and the second side being that portion of the tab sidewall opposite thereto.

Regarding claim 67, the examiner considers element 10 to represent a reinforcing polymer between the first and second fin sides.

Regarding claim 68, the examiner will consider the proximal end of the fin to be the curved corner of the tab (i.e., that portion of the tab located in the bottom left of Fig. 3).

Regarding claim 84, Healy shows an electrode 13 having a first face and a second face (the opposite sides of the conductive disk upon which the gel 17 is located as best seen in Fig. 6). A backing layer 14 is disposed over the first face of the electrode and an appendage (the electrical fitting post 16) is disposed on a first face of the electrode and extends through the backing layer.

5. Claims 1, 59-62, 64, 68, 69, 71, 72, 75-77, 79-81 are rejected under 35 U.S.C. 102(e) as being anticipated by Bishay et al. (Pat. No. 6,272,385).

Regarding claim 1, Bishay et al. disclose a lead electrode assembly comprising an electrode 24 having a proximal end and a distal end, and top and bottom surfaces (inherent in any multi-dimensional object), a backing layer 22 (or 42) positioned over the top of the electrode, and a fin 32 (or 48), wherein the backing layer forms the fin and the fin projects from the backing layer.

Regarding the recitation in the preamble concerning the use of a subcutaneously placed implantable cardioverter-defibrillator, the examiner considers such language to represent intended use for the lead electrode assembly.

Regarding claim 59, the examiner considers the fin to project substantially perpendicular from the side wall of the backing layer.

Regarding claim 60, if one defines the backing layer to generally comprise elements 22 and 28 (or alternatively elements 40 and 26)(see Fig. 2), then one can consider the "backing layer" to be attached directly to electrode 24 and be substantially the same size as the electrode.

Regarding claim 62, Bishay et al. disclose that polymers such as polyethylene coated polyester or polyethylene coated foil may be used in the construction of elements 22 or 42 (see col. 2, lines 56-61).

Regarding claim 64, the examiner considers element 40 to represent a cover disposed over backing layer 22 and fin 32 (alternately, one could consider elements 22 and 32 to represent a cover for backing layer 40).

Regarding claim 68, the examiner considers fin 32 (or 48) to have a proximal and a distal end with the proximal end of the fin sloped as best can be seen in Fig. 2.

Regarding claim 71, the examiner considers the fin of Bishay et al. to be by nature flexible such that it is capable of being folded to reduce the height of the fin. The claim does not require that the fin actually be folded, merely that the fin be flexible such that folding is possible.

Regarding claim 72, the examiner considers Fig. 3 to show a fin 52 formed from a backing layer 50 with the first and second sides of the fin connected at the top and bottom such that the fin is substantially tubular. In this case, the rightmost side of the backing layer 50 shown in Fig. 3 is folded back and attached to the left side.

Regarding independent claim 75, comments made in the rejection of claim 1 apply here as well.

Regarding claim 77, note the comments made in the rejection of claim 64.

Regarding claim 79, note the comments made in the rejection of claim 68.

Regarding independent claim 81, comments paralleling those made in the rejection of claim 1 apply here as well.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 62 and 63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Healy (Pat. No. 4,757,817) in view of Krasnow (Pat. No. 3,828,766).

Healy does not elaborate on the use of the polymer polyurethane as a material for the backing layer. Krasnow, however, discloses a substantially similar medical electrode wherein a polyurethane backing layer is employed (see col. 4, lines 42-57). Such a material is ubiquitously used in the construction of medical electrodes due to its lightweight, flexible and biocompatible nature. To therefore use polyurethane in the make-up of the substantially similar Healy backing layer would have been considered an obvious matter of design by those of ordinary skill in the medical electrode design arts.

8. Claims 69 and 86 are rejected under 35 U.S.C. 103(a) as being unpatentable over Healy (Pat. No. 4,757,817).

With regards to claim 69, Healy does not discuss the use of silicone as a material for the construction of the backing layer. Healy does, however, teach that the layer should be pliable (col. 3, lines 20-22). It goes without saying that the pad should be hypoallergenic as well since it is to be disposed on the skin. Silicone is well-known by medical electrode artisans to be both pliable and hypoallergenic, and thus entirely suitable for use in the manufacture of the Healy backing layer. The courts have long established that the selection of a known material based on its suitability for the intended purpose was a matter of obvious design (see *Sinclair & Carroll Co. v.*

Interchemical Corp., 325 U.S. 327, 65 USPQ 297 (1945). To use such a well-known material in the construction of the Healy device would have therefore been considered a matter of obvious design by those of ordinary skill in the art.

Concerning claim 86, Healy does not elaborate on the particular conductive metal used in the construction of the appendage. Platinum and titanium, however, are well-known conductive metals suitable for use in medical applications due to their recognized biocompatibility and conductive properties. As stated above, the courts have long established that the selection of a known material based on its suitability for the intended purpose was a matter of obvious design (see *Sinclair & Carroll Co. v. Interchemical Corp.*, 325 U.S. 327, 65 USPQ 297 (1945)). Any artisan desiring a non-irritating, highly conductive electrode interface would have therefore considered the use of such known materials as obvious.

9. Claim 65 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bishay et al. (Pat. No. 6,272,385).

Claim 65 is considered to be a product-by-process claim where the applicants are attempting to limit the claim in terms of how the product is made, rather than in terms of what the product is (see *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985)). The applicants have given no criticality to the use of a molding process in the construction of the cover. Any known manner of constructing the cover set forth by Bishay et al. (see the rejection of claims 1 and 64 above) would have been considered applicable as long as it was capable of producing a suitable sheet or cover layer. The ordinarily skilled artisan would have therefore considered the use of a molded cover as a matter of obvious design prerogative. Further, the cover of Bishay et al. is shown to cover at least a portion of the bottom of the electrode as best seen in Fig. 3.

Allowable Subject Matter

10. Claims 73, 74, 78, 82, 83 and 85 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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Regarding claim 73, the prior art of record does not appear to disclose a lead electrode assembly with a substantially tubular fin wherein the first and second sides of the fin are connected along a length of the proximal end such that the fin is closed at the proximal end and open at the distal end.

Regarding claim 78, there does not appear to be any impetus to modify the prior art of record to comprise a reinforcing polymer disposed between the fin and cover.

Regarding claim 82, there is no teaching in the prior art of record for including a fin with a rigid head and a flexible connector, the flexible connector attaching the rigid head to the backing layer.

Regarding claim 85, prior artisans do not disclose the use of a lead electrode assembly having an appendage with the recited rod comprising first and second extensions and a loop therebetween.

Conclusion

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

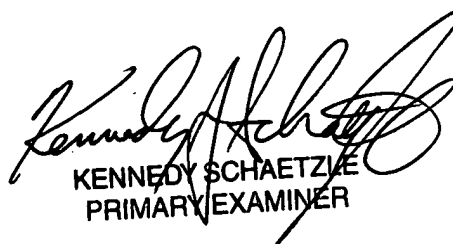
12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kennedy Schaetzle whose telephone number is 571 272-4954. The examiner can normally be reached on M-W and F from 9:30 -6:00.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached at 571 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

KJS
November 12, 2004



KENNEDY SCHAEETZLE
PRIMARY EXAMINER